

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Caffeine on Ileus After Laparotomy

Protocol summary

Study aim

Effect of Caffeine on Ileus After Laparotomy

Design

This study is a randomized controlled clinical trial with no corsair. In this study, which will be conducted in parallel groups, 84 patients who are candidates for laparotomy will be included in the study. Randomization will be done with the help of Randlist software.

Settings and conduct

This study will be performed in Imam Reza Hospital (Tabriz) with the participation of 84 patients. In this study, which was performed without corsaging, 84 patients were randomly divided into two groups; The first group will receive one caffeine tablet every eight hours and the control group will receive one placebo tablet every eight hours.

Participants/Inclusion and exclusion criteria

Inclusion criteria include (1) a candidate for laparotomy, (2) a hospitalized patient, and (3) the ability to take medication and food orally, and exclusion criteria include (1) caffeine sensitivity, (2) and heart rate. Hearts are more than 120 per minute (3) of emergency surgery.

Intervention groups

The intervention group will be given one caffeine tablet every eight hours and the control group will be given one placebo tablet every eight hours.

Main outcome variables

Intestinal movements and sounds

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140203016473N11**

Registration date: **2020-12-09, 1399/09/19**

Registration timing: **prospective**

Last update: **2020-12-09, 1399/09/19**

Update count: **0**

Registration date

2020-12-09, 1399/09/19

Registrant information

Name

Farzad Kakaei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 1317

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fkakaei@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Caffeine on Ileus After Laparotomy

Public title

Effect of Caffeine on Ileus After Laparotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for laparotomy Needs hospitalization Ability to take medicine and food by mouth

Exclusion criteria:

Caffeine sensitivity Heart rate greater than 120 beats per

minute Emergency surgery

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization is performed with Randlist software version 1.2 and participants are divided into two groups of intervention and control.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of medical sciences

Street address
Azadi Ave, Golgasht St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2020-01-20, 1398/10/30

Ethics committee reference number
IR.TBZMED.REC.1398.1140

Health conditions studied

1

Description of health condition studied
Intestinal diseases

ICD-10 code
A07

ICD-10 code description
Other protozoal intestinal diseases

Primary outcomes

1

Description
Intestinal movements and sounds

Timepoint
Three times a day, once every eight hours for three days

Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients applying for laparotomy will receive the intervention the day before surgery. The intervention will be such that they will consume one caffeine tablet every eight hours daily. Bowel sounds and movements will then be monitored for up to three days after surgery.

Category
Treatment - Drugs

2

Description
Control group: Patients applying for laparotomy will receive the intervention the day before surgery. The intervention will be such that they will take one placebo tablet every eight hours daily. Bowel sounds and movements will then be monitored for up to three days after surgery.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Surgery Ward of Imam Reza hospital

Full name of responsible person
Dr Farzad Kakaei

Street address
Golgasht Ave., Azadi Ave., Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hasan Soleimanpour

Street address

Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Farzad Kakaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available